BRAINLAB

Brainlab AG
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EU-DECLARATION OF CONFORMITY

Manufacturer	Brainlab AG
Manufacturing site (s)	Olof-Palme-Straße 9, 81829 Munich, Germany
SRN number	DE-MF-000006183
Medical device	Registration Fluoro 3D
Trade name(s)	Registration Software Fluoro 3D Auto-Registration Software 3D C-Arm
Intended Purpose	The device enables image guided surgery
Basic UDI-DI	4056481Fluoro3DLX
Regulation/Directive	EU 2017/745 EU 207/2012
Risk class	Class IIb
Rule according to Annex VIII	Rule 11, indent III
Standards/common specification	See Annex I
Product codes	MDA 0315, MDS 1009, MDT 2012
GMDN code	62783
EMDN code	Z12011482 SURGICAL NAVIGATION INSTRUMENTS - SOFTWARE ACCESSORIES
Notified Body	TÜV SÜD Product Service GmbH, Ridlerstr. 65, 80339 Munich, Germany
Notified Body Identification number	0123
EU Certificate	G10 037489 0059, valid until 2025-09-13

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We, Brainlab AG, declare under our sole responsibility that:

MDR

- the device specified above is a medical device according to Regulation 2017/745 Article 2 and meets the provisions of this regulation.
- the device complies with the General Safety and Performance Requirements stated in Annex I of Regulation 2017/745.
- the procedure referred to in Annex IX of Regulation 2017/745 has been followed.

EU 207/2012

- the device specified above is within the scope of Regulation 207/2012 on electronic information for use and meets the provisions of this Regulation

This declaration is valid from the date of signature.

Name	Function	Place, Date, Signature
Martin Immerz	Vice President R&D	Munich 16. Feb 2023

TOGETHER WE ARE MAKING MEDICAL TECHNOLOGY AND KNOWLEDGE MORE IMPACTFUL AND ACCESSIBLE TO PHYSICIANS AND THEIR PATIENTS.

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ANNEX I

REGISTRATION FLUORO 3D

STANDARDS / COMMON SPECIFICATIONS

Standard	Title
EN ISO 13485:2016 + AC:2018	Medical devices - Quality management systems - Requirements for regulatory purposes
ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
ISO 20417:2021	Medical devices — Information to be supplied by the manufacturer
IEC 62366-1:2015	Medical devices – Application of usability engineering to medical devices
IEC 62304:2006 + AMD1:2015	Medical device software - Software life-cycle processes
MDCG 2018-5	UDI Assignment to Medical Device Software
MDCG 2019-16	Guidance on cybersecurity for medical devices
MDCG 2020-1	Guidance on clinical evaluation (MDR) / Performance evaluation (IVDR) of medical device software
MDCG 2020-5	Guidance on clinical evaluation – Equivalence
IEC 80001-1:2010	Application of risk management for IT-networks incorporating medical devices – Part 1: Roles, responsibilities and activities
DICOM	Digital Imaging and Communications in Medicine (DICOM)

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ANNEX II

REGISTRATION FLUORO 3D

DEVICE IDENTIFIERS INCLUDED

UDI-DI	Name, Version	Tradename(s)
04056481143923	Registration Fluoro 3D, 1.5	Registration Software Fluoro 3D Auto-Registration Software 3D C-Arm